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*Attorneys for Plaintiff, Fresenius Medical Care Holdings, Inc.*

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

| | | |
|---|---|---|
| FRESENIUS MEDICAL CARE HOLDINGS, INC.<br>Plaintiff,<br>v.<br>SUVEN LIFE SCIENCES LTD.<br>Defendant. | ) | C.A. No. _____ |

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Fresenius Medical Care Holdings, Inc. ("FMCHI") for its Complaint against Suven Life Sciences Ltd. ("Suven") alleges as follows:

**NATURE OF ACTION**

1. This is a civil action for declaratory and injunctive relief against Suven for patent infringement under the Food and Drug and Patent Laws of the United States, arising from

Suven's submission of Abbreviated New Drug Application ("ANDA") No. 211038 to the Food and Drug Administration ("FDA").

2. In ANDA No. 211038, Suven seeks approval to market calcium acetate 667 mg capsules, a generic version of FMCHI's PhosLo® GelCaps calcium acetate drug product prior to the expiration of U.S. Patent Nos. 6,576,665 ("the '665 patent") and 6,875,445 ("the '445 patent") (together, the "patents-in-suit").

**THE PARTIES**

3. FMCHI is a New York corporation having its principal place of business at 920 Winter Street, Waltham, Massachusetts 02451.

4. Upon information and belief, Suven is an Indian company having a principal place of business in Hyderabad, Telangana India, and it also has a place of business at 1100 Cornwall Road, Monmouth Junction, New Jersey 08852. Upon information and belief, Suven has an authorized U.S. agent for its ANDA located at 1100 Cornwall Road, Monmouth Junction, New Jersey 08852.

**JURISDICTION AND VENUE**

5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202. Specifically, on information and belief, Suven included in ANDA No. 211038 a certification under Paragraph IV of Section 505(j)(2)(A)(vii) of the Federal Food, Drug, and Cosmetic Act, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the "Hatch-Waxman Act"), with respect to the '665 patent and the '445 patent, which are both assigned to FMCHI. Under the Hatch-Waxman Act, the filing of a so-called "Paragraph IV certification" with respect to a patent constitutes an act of patent infringement under 35 U.S.C. § 271(e)(2)(A). Accordingly, this case presents a question of federal law over which the Court has exclusive subject matter jurisdiction.

6. This Court has personal jurisdiction over Suven at least by virtue of the fact that Suven conducts business in New Jersey, has availed itself of the rights and benefits of New Jersey law, and/or has engaged in substantial and continuing contacts with New Jersey. In addition, this Court has personal jurisdiction over Suven because it has its primary U.S. place of business in New Jersey.

7. Suven is in the business of making and selling drug products in the United States.

8. On information and belief, Suven regularly and continuously transacts business within New Jersey, including by selling pharmaceutical products in New Jersey, either on its own or through an affiliate.

9. Suven has previously been sued in this judicial district without objection on the basis of lack of personal jurisdiction and has availed itself of the rights, benefits, and privileges of New Jersey by asserting counterclaims related to patent infringement in this judicial district in *Taro Pharmaceuticals North America, Inc. et al. v. Suven Life Sciences, Ltd. et al.*, Civil Action No. 11-cv-2452 (D.N.J.).

10. This Court further has personal jurisdiction over Suven because, on information and belief, Suven will engage in the manufacture, importation, marketing and sale of the Suven ANDA product in the United States, including in the state of New Jersey, if it is approved.

11. At least because, on information and belief, Suven is a foreign corporation, venue is proper in this jurisdiction under 28 U.S.C. §§ 1391 and 1400(b).

**INFRINGEMENT BY SUVEN**

12. FMCHI is the holder of New Drug Application ("NDA") No. 21-160, by which the FDA granted approval for the marketing and sale of FMCHI's PhosLo® GelCaps calcium acetate drug product. Suven's ANDA No. 211038 is based on FMCHI's NDA No. 21-160.

13. FMCHI is the assignee of the ’665 patent and the ’445 patent. A copy of the ’665 patent is attached as Exhibit A. A copy of the ’445 patent is attached as Exhibit B. The FDA’s official publication of approved drugs (the “Orange Book”) includes PhosLo® GelCaps together with the patents-in-suit.

14. The claims of the ’665 patent are valid, enforceable, and not expired.

15. The claims of the ’445 patent are valid, enforceable, and not expired.

16. Suven’s submission of ANDA No. 211038 constitutes infringement of the patents-in-suit. On information and belief, Suven included within its ANDA a Paragraph IV certification to the effect that the patents-in-suit are invalid, unenforceable, and/or would not be infringed by its proposed generic copy of FMCHI’s PhosLo® GelCaps calcium acetate drug product. The submission of this certification constitutes an act of infringement of one or more claims of both the ’665 patent and the ’445 patent because the proposed generic drug is covered by one or more claims of the ’665 patent and the ’445 patent, and/or because its use is covered by the ’665 patent and the ’445 patent. *See* 35 U.S.C. § 271(e)(2)(A).

17. By its letter dated March 28, 2019 (“Notice Letter”), Suven notified FMCHI of its ANDA filing seeking approval to engage in the commercial manufacture, use, and sale of generic calcium acetate product before the expiration dates of the patents-in-suit.

18. In the Notice Letter, Suven notified FMCHI that its ANDA contained a Paragraph IV certification alleging that in its opinion no valid claim of the patents-in-suit would be infringed by its proposed generic calcium acetate drug product.

19. This Complaint is being filed before the expiration of the forty-five days from the date FMCHI received the Notice Letter.

**COUNT I: INFRINGEMENT OF THE '665 PATENT**

20. Each of the preceding paragraphs 1 to 19 is incorporated as if fully set forth herein.

21. Upon information and belief, Suven intends to, and will, engage in the commercial manufacture, use and sale of its generic calcium acetate drug product promptly upon receiving FDA approval to do so.

22. Upon FDA approval of Suven's ANDA No. 211038, Suven will infringe one or more claims of the '665 patent, including but not limited to claims 1-5, by making, offering to sell, importing, or selling its proposed generic calcium acetate drug product in the United States, or by actively inducing or contributing to infringement by others, unless enjoined by this Court.

23. FMCHI has the right and standing to enforce the '665 patent and bring this action.

24. Suven had notice of the '665 patent at the time of its infringement. Suven's infringement has been, and continues to be, willful and deliberate.

25. FMCHI will be substantially and irreparably damaged and harmed if Suven's infringement is not enjoined. FMCHI does not have an adequate remedy at law.

**COUNT II: INFRINGEMENT OF THE '445 PATENT**

26. Each of the preceding paragraphs 1 to 25 is incorporated as if fully set forth herein.

27. Upon information and belief, Suven intends to, and will, engage in the commercial manufacture, use and sale of its generic calcium acetate drug product promptly upon receiving FDA approval to do so.

28. Upon FDA approval of Suven's ANDA No. 211038, Suven will infringe one or more claims of the '445 patent, including but not limited to claims 1, 2, 7, 35, and 36, by making, offering to sell, importing, or selling its proposed generic calcium acetate drug product in the

United States, or by actively inducing or contributing to infringement by others, unless enjoined by this Court.

29. FMCHI has the right and standing to enforce the ’445 patent and bring this action.

30. Suven had notice of the ’445 patent at the time of its infringement. Suven’s infringement has been, and continues to be, willful and deliberate.

31. FMCHI will be substantially and irreparably damaged and harmed if Suven’s infringement is not enjoined. FMCHI does not have an adequate remedy at law.

**PRAYER FOR RELIEF**

Accordingly, plaintiff respectfully requests the following relief:

a. A judgment declaring that Suven has infringed the ’665 patent and the ’445 patent, and that Suven’s making, using, selling, offering to sell, or importing of its generic calcium acetate drug product will infringe the ’665 patent and the ’445 patent;

b. A judgment providing that the effective date of any FDA approval for Suven to make, use or sell its generic calcium acetate drug product be no earlier than the date on which the ’665 patent and the ’445 patent expire;

c. A judgment permanently enjoining Suven from making, using, selling, offering to sell, or importing its generic calcium acetate drug product until after the expiration of the ’665 patent and the ’445 patent;

d. If Suven engages in the commercial manufacture, use, offer to sell, or sale of its generic calcium acetate drug product prior to the expiration of the ’665 patent and the ’445 patent, a judgment awarding FMCHI damages or other monetary relief, increased to treble the amount found or assessed, together with interest;

e. Attorney’s fees pursuant to 35 U.S.C. § 285;

f. Costs and expenses in this action; and

g. Such further and other relief as the Court may deem just and proper.

FRESENIUS MEDICAL CARE HOLDINGS, INC.

By its attorney,

*/s/ Peter A. Sullivan*

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*Fresenius Medical Care Holdings, Inc.*

Dated: May 13, 2019